

SEP 3 2002 K03 1847

May, 2002

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TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

May, 2002

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|--------------------------------|--|
| <u>Trade Name:</u> | Maxi-Cell biopsy needle |
| <u>Common Name:</u> | Biopsy needle |
| <u>Classification Name:</u> | Instrument, biopsy (per 21 CFR section 876.1075) |
| <u>Manufacturer's Name:</u> | Biopsy Sciences, LLC 1011 North Craycroft Road, Suite 302 Tucson, AZ 85711 |
| <u>Corresponding Official:</u> | Sharon Rockwell Vice-President RA/QA 5582 Chalon Road Yorba Linda, CA 92886 Phone: (714) 695-9269 Fax: (714) 779-0406 |
| <u>Predicate Device(s):</u> | Kendall/Sherwood Medical Plastic Hub Spinal Needle, K822630 and, Manan Westcott Biopsy Needles, K851838. |
| <u>Device Description:</u> | The biopsy needle is a single lumen needle, identical in design to the predicate, from Sherwood Medical. The shaft of the needle has been modified to provide additional sampling sites approximately 0.40inches proximal to the needle tip. Once the needle is positioned at the site of interest, the stylet is removed and the needle is manually advanced to obtain a freehand needle biopsy of tissue, or aspirate, while suction is applied with a syringe. Then as the needle is withdrawn, the side-sampling site will also remove tissue, allowing the physician to collect at least twice the amount of tissue sample typically removed by a biopsy needle. The needle is made of ASTM type 304 stainless steel, as is the stylet. |

Intended Use:

For use in fine needle biopsies of various soft organs and tissues, including, but not limited to, biopsies for breast, lung, thyroid, liver, pancreas, spleen, kidneys, and prostate tissue.

Technological
Characteristics:

The biopsy needles are available in 20-22 gauge sizes and lengths from 3 ½ to 9 inches. A stylet is provided with the needle to avoid coring tissue during advancement to the lesion site.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 2002

Ms. Sharon Rockwell
Vice President RA/QA
Biopsy Sciences, LLC.
5582 Chalon Road
YORBA LINDA CA 92886

Re: K021847

Trade/Device Name: Biopsy Sciences, LLC. Maxi-Cell Biopsy Needles
Regulation Number: 21CFR § 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: May 31, 2002
Received: June 5, 2002

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

TAB 3
INDICATIONS FOR USE

510(k) Number: K021847

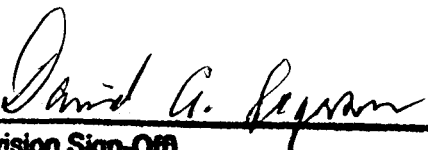
Device Name: Maxi-Cell Biopsy Needle

Indications for Use:

The Biopsy Sciences, LLC., Maxi-Cell Biopsy Needles are intended to be used for fine needle biopsies of various soft organs and tissues, including, but not limited to, biopsies for breast, lung, thyroid, liver, pancreas, spleen, kidneys, and prostate

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021847

☒ **Prescription Use**
(per 21 CFR 801.109)

or

☐ **Over-The-Counter Use**